

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	:	
	:	MDL NO. 1203
	:	
	:	
THIS DOCUMENT RELATES TO:	:	
	:	
SHEILA BROWN, et al.	:	
	:	CIVIL ACTION NO. 99-20593
v.	:	
	:	
AMERICAN HOME PRODUCTS CORPORATION	:	2:16 MD 1203
	:	

MEMORANDUM AND PRETRIAL ORDER NO.

Bartle, C.J.

May 11, 2007

Adrienne Walker ("Ms. Walker" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth, Inc.¹ seeks benefits from the AHP Settlement Trust ("Trust"). Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").²

1. Prior to March 11, 2002, Wyeth, Inc. was known as American Home Products Corporation.

2. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See (continued...)

To apply for Matrix Benefits, a claimant must submit a completed Green Form to the Trust. The Green Form consists of three parts. Part I of the Green Form is to be completed by the claimant or the claimant's representative. Part II is to be completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria in the Settlement Agreement. Finally, Part III is to be completed by the claimant's attorney if he or she is represented.

In July 2002, claimant submitted a completed Green Form to the Trust signed by her attesting physician Steven S. Gubin M.D. Dr. Gubin is no stranger to this litigation. According to the Trust, he has attested to at least 77 Green Forms on behalf of claimants seeking Matrix Benefits. Based on an echocardiogram dated April 1, 2002, Dr. Gubin attested in Part II of Ms. Walker's Green Form that she suffered from moderate mitral regurgitation and an ejection fraction in the range of 50% to 60%. Based on such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of \$556,216.

2(...continued)

Settlement Agreement §§ IV.B.2.b., IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrix applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period, or who took the drugs for 60 days or less, or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these diet drugs.

In the report of claimant's echocardiogram, Dr. Gubin stated that claimant had: "[m]oderate mitral regurgitation with normal left atrial size." Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22. Dr. Gubin also stated that claimant had an ejection fraction of 60%, which meets the definition of a reduced ejection fraction under the Settlement Agreement. See id. § IV.B.2.c.(2)(b).

In December 2003, the Trust forwarded the claim for review by Ralph Millsaps, M.D., one of its auditing cardiologists. In audit, Dr. Millsaps concluded that there was no reasonable medical basis for Dr. Gubin's finding that claimant had moderate mitral regurgitation because her echocardiogram demonstrated only physiologic regurgitation.³ In his certification, Dr. Millsaps stated the following: "[s]top frame tracing done just before P wave[.] [L]ow Nyquist of 54 cm/sec does not represent cine loops."⁴

3. Physiologic regurgitation is defined as a "[n]on-sustained jet immediately (within 1 cm) behind the annular plane or <+ 5% RJA/LAA." See Report of Auditing Cardiologist Opinions Concerning Green Form Questions at Issue, at 2.

4. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). The Trust did not contest the attesting physician's finding of a reduced ejection
(continued...)

Based on Dr. Millsaps' diagnosis of physiologic regurgitation, the Trust issued a post-audit determination denying Ms. Walker's claim on February 5, 2004. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant sent a letter to the Trust on April 23, 2004 to contest this adverse determination.⁵ In contest, claimant submitted a letter from Keith G. Anderson, M.D. Claimant asserted that Dr. Anderson's letter established that her regurgitation "is more than physiologic." In his letter, Dr. Anderson stated that:

Mitral regurgitation is mild (RJA/LAA > 5% and < 20%). The attesting cardiologist overestimated the RJA by including low velocity monochromatic signals. The mitral jet height is > one cm from the valve plane, and, therefore, the regurgitation is more than physiologic.

The Trust then issued a final post-audit determination, again denying Ms. Walker's claim, on October 6, 2004. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7; PTO No. 2807,

4(...continued)
fraction, which is one of the complicating factors needed to qualify for a Level II claim. Thus, the only issue is claimant's level of mitral regurgitation.

5. Claims placed into audit on or before December 1, 2002 are governed by the Audit Policies and Procedures, as approved in Pretrial Order No. ("PTO") 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Rules for the Audit of Matrix Compensation Claims, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Walker's claim.

Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Ms. Walker's claim should be paid. On May 20, 2005, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 5243 (May 20, 2005). The parties have now briefed the matter.

In support of her claim, Ms. Walker argues that her claim should be paid because she was "diagnosed with Moderate Mitral Regurgitation" and the Trust untimely issued her final post-audit determination. In response, the Trust argues that claimant failed to meet her burden of establishing a reasonable medical basis for her claim and that its untimely issuance of claimant's final post-audit determination does not entitle claimant to Matrix Benefits.

After reviewing the entire Show Cause Record before us, we find claimant's arguments without merit. First, and of crucial importance, claimant does not dispute the diagnosis offered by the auditing cardiologist, Dr. Millsaps, that she does not have moderate mitral regurgitation. Despite the opportunity in the contest period to present additional evidence in support of her claim, Ms. Walker does not refute or respond to Dr. Millsaps' specific findings. Equally significant, claimant's own reviewing cardiologist, Dr. Anderson, concluded that claimant's mitral regurgitation was mild because the attesting physician "overestimated the RJA by including low velocity monochromatic

signals."⁶ On this basis alone, claimant has failed to meet her burden of demonstrating that there was a reasonable medical basis for her claim.

We also reject claimant's assertion that she should receive Matrix Benefits due to the Trust's untimely issuance of its final post-audit determination. According to the Trust, claimant's initial letter contesting the post-audit determination was "misdirected within the Trust." As a result, the Trust issued its final post-audit determination beyond the thirty (30) day period set forth in the Audit Rules. See Audit Rule 18(c). Although claimant argues that she should be paid due to the late issuance of the final post-audit determination, we are unwilling to order payment on an uncompensable claim without, at a minimum, some showing of prejudice. Claimant has failed to demonstrate any prejudice resulting from the untimely issuance of the Trust's final post-audit determination.

For the foregoing reasons, we conclude that claimant has not met her burden in proving that there is a reasonable medical basis for finding that she had moderate mitral regurgitation. Therefore, we will affirm the Trust's denial of Ms. Walker's claim for Matrix Benefits.

6. Dr. Anderson's additional finding that claimant's regurgitation was more than physiologic is irrelevant for resolution of this claim because claimant must have moderate mitral regurgitation to receive Level II Matrix benefits. See Settlement Agreement § IV.B.2.c.(2)(b).

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AND NOW, this 11th day of May, 2007, for the reasons set forth in the accompanying Memorandum, it is hereby ORDERED that the final post-audit determination of the AHP Settlement Trust is AFFIRMED and that the Level II Matrix claim submitted by claimant Adrienne Walker is DENIED.

BY THE COURT:

/s/ Harvey Bartle III

C.J.